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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY/PROSECUTOR	CLASSIFICATION
09/711,782	11/15/2000	Rex M. Bitner	10026-9204	U.S.

23510 7590 04/01/2003

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EXAMINER

RILEY, JEZIA

ART. NO.	PAPER NUMBER
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DATE MAILED 04/01/2003

124

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/711,782

Applicant(s)

BITNER ET AL.

Examiner

Jezia Riley

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on 21 February 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☐ Claim(s) 1-51 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) 24-51 is/are allowed.
- 6) ☒ Claim(s) 1-4,7,8,13-16,18 and 19 is/are rejected.
- 7) ☒ Claim(s) 5,6,9-12,17 and 20-23 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

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DETAILED ACTION

Response to Remarks

1. Applicants' arguments and amendments, filed on 2/21/03, have been approved and entered. They have been fully considered but they are not deemed to be persuasive. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either newly applied or reiterated. They constitute the complete set presently being applied to the instant application.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to

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consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

3. Claims 1-4, 7, 8, 13-16, 18, and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Smith et al. (6,027,945) in view of Schneider et al. (4,925,818).

Smith et al. discloses methods of isolating biological target materials using silica magnetic particles (col. 5-7). The methods provide for isolating biological target materials, particularly nucleic acids, such as DNA or RNA or hybrid molecules of DNA and RNA, from other substances in a medium using silica magnetic particles. The methods involve forming a complex of the silica magnetic particles and the biological target material in a mixture of the medium and particles, separating the complex from the mixture using external magnetic force, and eluting the biological target material from the complex. The preferred embodiments of magnetic silica particles used in the methods and kits of the present invention are capable of forming a complex with at least 2 mug of biological target material per milligram of particle, and of releasing at least 60% of the material from the complex in the elution step of the method. The methods produce isolated biological target material which is substantially free of contaminants, such as metals or macromolecular substances, which can interfere with further processing or analysis, if present. First, a mixture is formed comprising the medium including plasmid DNA, the siliceous-oxide coated magnetic particle, and a chaotropic salt. The concentration of chaotropic ions in the mixture formed is preferably between about 0.1 M and 7 M, but more preferably between about 0.5 M and 5 M. The

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concentration of chaotropic ions in the mixture must be sufficiently high to cause the biological target material to adhere to the silica magnetic particles in the mixture, but not so high as to substantially denature, to degrade, or to cause the target material to precipitate out of the mixture.

The biological target material isolated using the method can be obtained from eukaryotic or prokaryotic cells in culture or from cells taken or obtained from tissues, multicellular organisms including animals and plants; Cells will be lysed and the lysate usually processed in various ways familiar to those in the art to obtain an aqueous solution of DNA or RNA, to which the separation or isolation methods are applied. The DNA or RNA, in such a solution, will typically be found with other components, such as proteins, RNAs (in the case of DNA separation), DNAs (in the case of RNA separation), or other types of components.

Schneider et al. discloses a ligand specific to a bioactive substance to be purified fixed, via a connecting silane, to a mineral particulate carrier chosen from among SiO_2 , Al_2O_3 , ZrO_2 and TiO_2 , the particles of the carrier being submicronic, non-porous and having a large specific surface. The carrier is contacted with an aqueous extract containing inter alia the bioactive substances, for the time required for the substance to become specifically fixed to the carrier. The carrier is then separated and the desired bioactive substance is isolated by desorption (see abstract and col. 4-5 for example).

Therefore it would have been obvious at the time the invention was made to one of ordinary skill in the art to provide silanized silica matrices as taught by Schneider for the method of Smith et al. the motivation is that the method according to Schneider et

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al. as defined in their claim 1 obviates the disadvantages as discussed in col. 2 mainly the low fixation capacity and the slowness of the adsorption and desorption steps and can substantially increase the specific extraction yield. Furthermore, the rate at which the products to be extracted are fixed on the substrate is high and therefore the method is more economic to use. Finally the method can without difficulty be used for treating relatively large quantities of substances to be extracted, in contrast to earlier techniques. Furthermore the cost of non-porous submicronized silica is about a thousand times lower than the cost of carriers having standardized pores as generally used for purification by adsorption. Contrary to expectation, the non-porous submicronic particles used according to their invention are easily separated by filtration after being grafted by a ligand (col 2 lines 48-68 and col. 3 lines 1-6)

4. Claims 5, 6, 9-12, 17, 20-23 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

5. Claims 24-51 are allowed.

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jezia Riley whose telephone number is 703-305-6855.

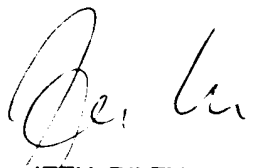
The examiner can normally be reached on 9:30AM - 5:00PM.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on 703-308-1119. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 for regular communications and 703-308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

March 31, 2003


JEZIA RILEY
PRIMARY EXAMINER